

Remarks

In a Communication mailed November 10, 1993 in the subject application, the Examiner stated that this application fails to comply with the requirements of 37 C.F.R. §§1.821 through 1.825 (hereinafter the "Rules") for the following reason:

Applicant has not complied with the requirements for Patent applications containing amino acid sequence disclosures. Applicant needs to submit all of the permutations of the peptides recited in the claims as individual sequences. For example, for the sequence listed in claim 1, every permutation of the instant formula needs to be submitted separately, eg. slfaag, etc.

Applicants respectfully disagree with the Examiner's contention. No such submission is required by the rules.

Claims 1, 13, 21 and 26 in the subject application contain a formula having positions for six amino acids, wherein there are seven possibilities for amino acid one, five possibilities for amino acid two, two possibilities each for amino acids three and six, and at least twenty possibilities for amino acids four and five. The rules require sequence listings only for

[a]ny peptide or protein [of four or more amino acids] that can be expressed as a sequence using the symbols in §1.822(b)(2) in conjunction with a description elsewhere in the "Sequence Listing" to describe, for example, modified linkages, cross links and end caps, non-peptidyl bonds, etc.

See 37 C.F.R. §1.821(a)(2). Thus, any peptide or protein that cannot be expressed by such a sequence is not embraced by the Rules. Since no symbol is available in §1.822(b)(2) to represent a selection of two, five or seven amino acids at a single residue, no single sequence listing could represent the formula of claim 1, and that formula is therefore not encompassed by the Rules.

The Examiner's solution -- to require applicants to enumerate and provide a separate listing for each permutation or combination represented by the formula of claim 1 -- is clever, but is not required or even suggested by the Rules. Whereas 37 C.F.R. §1.822(b)(1) lists symbols for every possible permutation or combination of nucleotides at a given residue (thus enabling multiple combinations of polynucleotides to be encoded by one single sequence); §1.822(b)(2), by contrast, offers no symbol for combinations of amino acids. Read in conjunction with the portion of §1.821(a)(2) reproduced above, it is evident that

sequence listings encompassing multiple permutations of amino acids are not intended to be covered by the rules.


Nothing in the rules even remotely suggests that this deficiency should be resolved by requiring applicants to enumerate each permutation of amino acids as a single sequence. Because the formula of claim 1 has seven possibilities for amino acid one, five possibilities for amino acid two, two possibilities each for amino acids three and six, and at least twenty possibilities for amino acids four and five, there would be a minimum of 56,000 sequences required by the Examiner as encoded by this formula. Even if "Xaa" is used to express the unknown amino acids at positions four and five, 140 sequences would still be required. Applicants submit that this is an unreasonable requirement and does not conform to the spirit or intention of the sequence listing requirements.

#### Conclusion

The formula in claims 1, 13, 21 and 26 is not encompassed by 37 C.F.R. §1.821-- .825. Nor do the Rules require each possible sequence encoded in this formula to be represented by an individual sequence listing.

Respectfully submitted,

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